

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01N-0437]

**Agency Information Collection Activities; Proposed Collection; Comment Request;
New Animal Drugs for Investigational Use**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for new animal drugs for investigational use.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. Collection of information is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 (c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

New Animal Drugs for Investigational Use—21 CFR Part 511 (OMB Control Number 0910–0117)—Extension

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act), for approval of new animal drugs. Section 512(j) of the act (21 U.S.C. 360b(j)), authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at part 511 (21 CFR part 511). A sponsor must submit to FDA a notice of claimed investigational exemption (INAD), before shipping the new animal drug for clinical tests in animals. The INAD must contain,

among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any nonclinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe, and that distribution is controlled to prevent potential abuse. The agency utilizes these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical profession. Respondents to this collection of information are the persons who use new animal drugs investigationally.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|-----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 511.1(b)(4) | 190 | 6 | 1,147 | 8 | 9,176 |
| 511.1(b)(5) | 190 | 1.5 | 287 | 140 | 40,180 |
| 511.1(b)(6) | 190 | .005 | 1 | 250 | 250 |
| 511.1(b)(8)(ii) | 190 | .005 | 1 | 20 | 20 |
| 511.1(b)(9) | 190 | .16 | 30 | 8 | 240 |
| Total | | | | | 49,866 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|-----------------|----------------------|------------------------------------|----------------------|------------------------|-------------|
| 511.1(a)(3) | 190 | 7.5 | 1,434 | 9 | 12,906 |
| 511.1(b)(3) | 190 | 10 | 1,912 | 1 | 1,912 |
| 511.1(b)(7)(ii) | 190 | 2 | 956 | 3.5 | 3,346 |
| 511.1(b)(8)(i) | 190 | 4 | 956 | 3.5 | 3,346 |
| Total | | | | | 21,510 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on agency communication with industry.

Additional information needed to make a final calculation of the total burden hours (i.e. the number of respondents, the number of recordkeepers, the number of INAD applications received, etc.) is derived from agency records.

Dated: 10/9/01
October 9, 2001.

Margaret M. Dotzel

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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